DARWIN EU® – Paracetamol prescribing and paracetamol overdose in Europe: a descriptive analysis of trends and patient characteristics

First published: 22/05/2025

Last updated: 22/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000584

Study ID

1000000584

DARWIN EU® study

Yes

Study countries

- ☐ Denmark
- ☐ France
- ☐ Germany

- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden

Study description

Paracetamol (acetaminophen) is one of the most widely used medicines worldwide and is available over the counter in the European Union.
It is one of the most common causes of drug poisonings and can result in severe hepatic failure.
Different regulatory interventions at national level have occurred to reduce the incidence of paracetamol overdose, but it is uncertain how paracetamol is prescribed across Europe and to what extent prescription may be involved in poisonings.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Berta Raventos

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/03/2025

Actual: 24/03/2025

Study start date

Planned: 05/05/2025

Actual: 05/05/2025

Date of final study report

Planned: 30/09/2025

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective cohort studies will be conducted using routinely collected health data from 8 databases.

Main study objective:

The aim of the study is to provide an overview of paracetamol prescribing and paracetamol overdose in the selected European databases, and to characterise patients presenting with paracetamol overdose.
The specific objectives of the study are:
1. To examine the incidence/prevalence of paracetamol prescribing (overall, and by age, sex, formulation and country/database).
2. To examine the incidence of paracetamol overdose (overall, and by age, sex, country/database).
3. To characterise patients with paracetamol overdose, in terms of comorbidities, co-prescribed medications, prior paracetamol prescription, and incidence of short-term complications and mortality.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
PARACETAMOL

Population studied

Short description of the study population
The source population will comprise all individuals present in the database at any time during the period from 1st of January 2010 to 31st of December 2023 (or last year with complete observation). All patients will need to have at least

365 days of data visibility prior to index date. Therefore, children aged <1 year will be excluded.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Danish Health Data Registries

InGef Research Database

Integrated Primary Care Information (IPCI)

Norwegian Linked Health registry at University of Oslo

Data source(s), other

Hospital Universitario 12 de Octubre, Health Impact - Swedish Population Evidence Enabling Data-linkage

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown